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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/662,008

09/11/2003

Michael Thomas Riebe

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04/03/2007

GLAXOSMITHKLINE

CORPORATE INTELLECTUAL PROPERTY, MAI B475

FIVE MOORE DR., PO BOX 13398

RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

EREZO, DARWIN P

ART UNIT

PAPER NUMBER

3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/03/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/662,008	RIEBE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Darwin P. Erez	3731	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,6-13 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-13 and 17-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/05/2006 has been entered.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 2, 6-13 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,421,492 to Barger et al in view of US 6,253,762 to Britto.

(claims 1 and 12) Barger discloses an aerosol container/inhalation device comprising:

a vial body containing an aerosol formulation of a suspension of a medicament in a hydrogen-containing fluorocarbon liquid propellant (col.1 , lines 25-30; the incorporated by reference to Johnson discloses a fluorinated propellant);

a valve, a shown in Fig. 3, the valve comprising:

a valve body defining a metering chamber 7,

a transfer passage 9,

and a dispensing means 19.

Barger is silent with regards to the metering chamber being made from a plastic material which is a mixture of fluorinated polymer and a non-fluorinated polymer. However, Barger does disclose the metering chamber or the valve stem being made from a metal or a plastic material (col. 3, lines 45-50).

Britto discloses a similar type of aerosol container comprising a vial body containing an aerosol formulation of a medicament (fluticasone propionate; col. 2, lines 45-55) in a hydrogen-containing fluorocarbon liquid propellant (1,1,1,2-tetrafluoroethane; col. 4, lines 18-20); a valve 3 for dispensing a metered amount of the aerosol; wherein the valve consists of parts that are made of a metallic material (col. 4, lines 55-59); wherein the part or all of the internal metallic surfaces of the aerosol container is coated with a fluorocarbon in combination with one or more non-fluorocarbon polymers (col. 5, lines 50-57). The coating will help reduce or eliminate the problem of drug adhesion on the internal surfaces of the aerosol container.

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the metering chamber of Barger to include the coating disclosed by Britto because it would help reduce or eliminate the problem of drug adhesion on the internal surfaces of the aerosol container.

The modified device of Barger now discloses a metering chamber having a surface that is coated with a mixture of fluorinated polymers and non-fluorinated polymers. Since a "chamber" is defined as "an enclosed space or cavity" and that the coating is now the structure that defines said "enclosed space or cavity, then the Examiner is viewing the "metering chamber formed by the coating" as being made from fluorinated polymer and non-fluorinated polymer.

With regards to the limitation of "with the proviso that the surface of the metering chamber in contact with the aerosol formulation is not coated with a fluorinated material", the Examiner is treating said limitation as a product by process limitation. As set forth in MPEP 2113, product by process limitations are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a rejection may be made and the burden is shifted to applicant to show an unobvious difference. In this case, the applicant is claiming that the metering chamber is not made by coating a surface with fluorinated hydrocarbons and non-fluorinated hydrocarbons. However, based on the applicant's specification, the metering chamber is taught as being formed by known moulding techniques or by applying a coating of fluorinated hydrocarbons and non-fluorinated hydrocarbons. Regardless of the process, the end result structure is still

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a metering chamber having fluorinated hydrocarbons and non-fluorinated hydrocarbons.

As stated above, the modified metering chamber of Barger defines an enclosed space or cavity, wherein the structure defining said metering chamber (the coating) is made with fluorinated hydrocarbons and non-fluorinated hydrocarbons.

(claims 2 and 13) Britto is silent with regards to the weight percentage of the fluorinated polymer. However, Britto teaches that the fluorinated polymer is coated onto the valve formed from non-fluorinated polymer. Therefore, it would have been obvious to one of ordinary skill in the art to provide a coating of about 5% weight of the valve since discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

(claims 6-8) Barger is silent with regards to the medicament being fluticasone propionate in a propellant comprising 1,1,1,2-tetrafluoroethane that is free of adjuvants. However, Britto discloses fluticasone propionate as a medicament (col. 2, lines 45-55) mixed in 1,1,1,2- tetrafluoroethane that is free of adjuvants (col. 4, lines 18-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to made use the medicament and propellant of Britto in the modified device of Barger because the use of a particular medicament and propellant is merely dependent upon the intended therapy for a patient.

(claims 9 and 17) The limitation of "wherein the metering chamber is moulded from the plastics material" is also being treated as a product by process limitation. Please see the rejection to claim 1. The modified device of Barger teaches a metering chamber that is formed by a coating of plastic polymers.

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(claims 10, 11, 18 and 19) Britto discloses the fluorocarbon being PTFE (col. 4, line 67) and the non-fluorocarbon being acetal (col. 4, line 57).

(claim 20) The device of Barger is a metered dose inhaler.

### ***Response to Arguments***

5. Applicant's arguments with respect to claims 1, 2, 6-13 and 17-20 have been considered but are moot in view of the new ground(s) of rejection.


### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who's telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Darwin P. Erez  
Examiner  
Art Unit 3731

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